

**IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
Alexandria Division**

H. LUNDBECK A/S,

Plaintiff,

v.

UNITED STATES PATENT AND
TRADEMARK OFFICE,

Defendant.

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Case No. 1:23-cv-1105 (PTG/WEF)

MEMORANDUM OPINION AND ORDER

This matter comes before the Court on Plaintiff's Motion for Summary Judgment and Defendant's Cross-Motion for Summary Judgment. Dkts. 28, 34. Pursuant to Fed. R. Civ. P. 56, Plaintiff and Defendant both argue that they are entitled to summary judgment as to the U.S. Patent and Trademark Office ("USPTO")'s decision to calculate a patent term adjustment ("PTA") of zero (0) rather than ninety-one (91) for U.S. Patent No. 11,059,822. *See id.* For the reasons that follow, this Court will deny Plaintiff's Motion for Summary Judgment (Dkt. 28) and grant Defendant's Cross-Motion for Summary Judgment (Dkt. 34).

Statutory Background

The patent process begins when an applicant files an application with the USPTO. *See* 35 U.S.C. § 111. Under the Patent Cooperation Treaty ("PCT"), an applicant can file one patent application, an international application, with the USPTO and have that application acknowledged in other contracting states to the PCT. *See Actelion Pharms., Ltd. v. Lee*, 216 F. Supp. 3d 680, 682 (E.D. Va. 2016), *aff'd*, 881 F.3d 1339 (Fed. Cir. 2018). An international application then enters the national stage of examination before the USPTO after the applicant timely provides certain documents and fees as prescribed by statute. *See* 37 C.F.R. § 1.491(b). Pursuant to 35 U.S.C. §

371(f), unless an applicant expressly requests an earlier commencement date of the national stage application, the national stage is considered to have commenced thirty months after the priority date of the international application. *See* PCT Art. 22(1).

“The life of a patent, the period of time during which the exclusive nature of a patent is in effect, is measured in years and days and is referred to as the ‘term’ of the patent or ‘patent term.’” *Supernus Pharms., Inc. v. Iancu*, 913 F.3d 1351, 1352 (Fed. Cir. 2019). In 1994, Congress amended the Patent Act to change the length of a patent term from seventeen (17) years, measured from the date the patent is issued, to 20 years, measured from the earliest filing date of the patent application. *See Gilead Scis., Inc v. Lee*, 778 F.3d 1341, 1343–44 (Fed. Cir. 2015). To address the effect of potential delays in the patent application process on the patent term, Congress amended the Patent Act in 1999 and passed the PTA statute (codified at 35 U.S.C. § 154(b)). *Id.* at 1344.

Section 154(b) of the statute grants the USPTO the authority to adjust the patent term by adding days for delays attributable to the agency. *See* 35 U.S.C. § 154(b)(1). Section 154(b)(1) identifies three types of delays caused by the USPTO, referred to as A, B, and C Delays. *Supernus*, 913 F.3d at 1353; § 154(b)(1)(A)–(C). Relevant here is a type A Delay, which applies when the USPTO fails to provide a notification under 35 U.S.C. § 132 or a notice of allowance within fourteen months of the patent application’s filing date. 35 U.S.C. § 154(b)(1)(A)(i). “[T]he term of the patent shall be extended 1 day for each day” the USPTO fails to meet its response deadline. *Id.*

The statute, however, provides that the USPTO may reduce the PTA to account for delays caused by the patent applicant. *Id.* § 154(b)(2)(C). Specifically, the statute allows for a reduction of the total amount of PTA for A, B, and C Delays by the number of days equal to the period of

time that “the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” *Id.* § 154(b)(2)(C)(i). The statute expressly recognizes that with respect to type B Delays, an applicant fails to “engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any period of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, or other request[.]” *Id.* § 154(b)(2)(C)(ii). Excluding this provision, the statute provides that the Director of the USPTO “shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” *Id.* § 154(b)(2)(C)(iii).

The Director of the USPTO has issued such regulations under 37 C.F.R. § 1.704. Relevant here is Rule 1.704(c)(13) which provides that an applicant fails to engage in reasonable efforts to conclude processing or examination of an application if the applicant:

Fail[s] to provide an application in condition for examination as defined in paragraph (f) of this section within eight months from . . . the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is eight months from . . . the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application and ending on the date the application is in condition for examination as defined in paragraph (f) of this section[.]

37 C.F.R. § 1.704(c)(13). Rule 1.704(f) provides that “[a]n international application is in condition for examination when it has entered the national stage as defined in § 1.491(b), and includes a specification, including at least one claim and an abstract (§ 1.72(b)), and has papers in compliance with § 1.52[.]” *Id.* § 1.704(f). Rule 1.52 states, in relevant part, that all papers of a patent application must be “[p]resented in a form having sufficient clarity and contrast between the paper

and the writing thereon to permit the direct reproduction of readily legible copies in any number . . . by use of digital imaging and optical character recognition.” *Id.* § 1.52(a)(1)(v).

After issuance of the patent, the PTA for the patent is calculated as “the sum of the delays caused by the USPTO and the applicant.” *Californiaa v. Hirshfeld*, No. 1:20-cv-985, 2021 WL 6196996, at *2 (E.D. Va. Dec. 30, 2021), *aff’d*, 2022 WL 16729429 (Fed. Cir. Nov. 7, 2022). If the applicant is dissatisfied with the PTA determination, the applicant may file a request for reconsideration with the USPTO pursuant to 35 U.S.C. § 154(b)(3)(B)(ii). *Id.* at *2. Following the USPTO’s final PTA determination, the applicant may seek judicial review by the United States District Court for the Eastern District of Virginia. *See id.* (citing § 154(b)(4)(A)).

Factual and Procedural Background

H. Lundbeck A/S (“Plaintiff”) is a global pharmaceutical company specializing in brain diseases. Dkt. 1 (“Compl.”) ¶ 4. Plaintiff is the assignee of U.S. Patent No. 11,059,822 (the “’822 patent”). *See* AR 5.¹ On November 15, 2017, Plaintiff filed an international patent application (No. PCT/US2017/061870), that later became the ’822 patent. *See* AR 99, 113. However, Plaintiff claimed priority to a provisional application (No. 62/423,102) filed on November 16, 2016. *See id.* The application entered the national stage on May 10, 2019 as Application No. 16/349,047 (“the ’047 Application”). *See* AR 93. Plaintiff, however, did not request earlier commencement of the national stage, and as such, the national stage commenced on May 16, 2019, thirty months after the claimed priority date of November 16, 2016. *See* AR 1 (listing the commencement date as 5/16/2019); *see also* Dkt. 29 (“Pl. SUF”) ¶ 2.²

¹ References to “AR” followed by a number indicates the page number in the Administrative Record (Dkts. 26, 27) where the cited information may be found.

² Plaintiff’s statement of undisputed fact regarding the commencement date of the national stage application being 30 months from the priority date of November 16, 2016 is not disputed by Defendant. *See* Dkt. 35 ¶ 2 (“The proffered fact in the last sentence is undisputed.”).

On March 11, 2020, the USPTO mailed Plaintiff a Formalities Letter, directing Plaintiff to file corrected application papers. AR 469–70. The Formalities Letter identified the following defect(s) in the '047 Application:

The application is not in compliance with 37 CFR 1.52 and PCT Rule 11 because pages 80-84, AND 139 CONTAIN(S) SHADING IN THE TABLE(S). Application papers (including any electronically submitted papers) must be presented in a form having sufficient clarity and contrast between the background of the paper and the writing thereon to permit the Office to electronically reproduce the papers by use of digital imaging and optical character recognition. *See* 37 CFR 1.52(a)(1)(v) and PCT Rules 11.2(a) and 11.9(d).

AR 469. The Formalities Letter instructed Plaintiff to file the corrected application papers (as well as pay additional claim fees) within two months of the date of the letter or obtain an extension of time by filing a petition and fee in accordance with the provisions of 37 C.F.R. § 1.136(a). AR 470.³ On June 5, 2020, Plaintiff responded to the Formalities Letter. AR 473. Plaintiff's response included the filing of corrected application papers that removed all shading from the table headers. AR 481, AR 711–15, AR 770–71.

On June 12, 2020, the USPTO issued a notice of acceptance of the '047 Application pursuant to 35 U.S.C. § 371 and 37 C.F.R. § 1.495. AR 788–89. On November 27, 2020, the USPTO issued its first Office action with respect to the '047 Application. AR 794–800. Then, on March 10, 2021, the USPTO issued a notice of allowance, noting that prosecution of the merits of the '047 Application had concluded, and that the application had been examined and allowed for issuance as a patent. *See* AR 1168.

³ While the actual March 11, 2020 Formalities Letter did not explicitly state that Plaintiff could respond within three months for a fee, and only references seeking an extension pursuant to 37 C.F.R. § 1.136(a), the parties agree that the notice allowed Plaintiff to respond within three months for a fee. *See* Pl. SUF ¶ 10; Dkt. 35 ¶ 10.

On June 23, 2021, the USPTO issued a notification to Plaintiff that the PTA under 35 U.S.C. § 154(b) for the '822 patent would be four (4) days. AR 1232. On August 25, 2021, Plaintiff filed a request for reconsideration of the PTA, requesting a PTA of 91 days. AR 1236. As its basis for the requested PTA, Plaintiff explained that it believed it was entitled to credit for the sum of 134 days accounting for the USPTO's delay in examining the '047 Application within the statutorily defined fourteen-month period from the date of commencement, subject to a reduction of 43 days accounting for the days following the notice of allowance when Plaintiff filed its information disclosure statement on March 11, 2021 and its corrected applicant data sheet on April 22, 2021. AR 1237.

On February 7, 2022, the USPTO redetermined that the PTA due to Plaintiff was 58 days. AR 1243. The USPTO agreed with Plaintiff that 134 days were attributed to the USPTO as "A delay" under 35 U.S.C. § 154(b)(1)(A). AR 1244. The agency also agreed that 43 days were attributed as applicant delay under 37 C.F.R. § 1.704(c)(10), and pursuant to 35 U.S.C. § 154(b)(2)(C), for the period beginning March 11, 2021 (the day after the notice of allowance was issued and when Plaintiff filed its information disclosure sheet) and ending April 22, 2021 (when Plaintiff filed its amended applicant data sheet). AR 1244–45. However, the USPTO found that an additional 33 days were attributed as applicant delay under 37 C.F.R. § 1.704(c)(13) "for the period beginning January 17, 2020 (day after the date that is eight months from the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application) and ending on February 18, 2020 (date the application is in condition for examination as defined in § 1.704(f))." AR 1245. According to the USPTO, Plaintiff had failed to provide the '047 Application in condition for examination as defined in 37 C.F.R. § 1.704(f) within eight months of the commencement date, and as such, every day thereafter until the application was in condition

for examination constituted a day of applicant delay. *See* AR 1246. In sum, the USPTO found that 76 days were attributed to applicant delay and subtracted these number of days from the days attributed to the USPTO's delay in assessing a PTA of 58 days. *Id.*

On April 13, 2022, the USPTO *sua sponte* issued a second redetermination of the PTA, concluding that the PTA was actually 0 days. AR 1257. In recalculating the PTA, the USPTO offered the following explanation:

The prior decision dated February 7, 2022, incorrectly affirmed the calculation of 33 days of applicant delay under 37 CFR 1.704(c)(13) for the period beginning on January 17, 2020, and ending on February 18, 2020. Upon further review of the record, the Office finds the application was not in a condition for examination as defined under 37 CFR 1.704(f) until June 5, 2020.

AR 1260. Accordingly, the USPTO determined that under 37 C.F.R. 1.704(c)(13), 141 days of applicant delay was appropriate for Plaintiff's failure to submit the application in condition for examination between the period of January 17, 2020 and June 5, 2020. AR 1559. In sum, the USPTO calculated 134 days of A Delay, 184 days of applicant delay, and subtracted the two to determine a PTA of 0 days. AR 1262. This second redetermination superseded and replaced the prior February 7, 2022 decision. AR 1257.

On November 9, 2022, Plaintiff filed a second request for reconsideration, once again arguing that Plaintiff was entitled to a PTA of 91 days. AR 1268. Plaintiff contended that it had satisfied the requirements of 37 C.F.R. § 1.704(c)(13) and § 1.704(f) as of the commencement date of May 16, 2019. AR1270. Plaintiff argued that 37 C.F.R. § 1.52(a)(1)(v) does not prohibit the use of shading in tables and that in compliance with the regulation, the tables on pages 80–84 and 139 of the '047 Application had sufficient clarity and contrast between the paper and writing even though they contained shading. AR 1273. Plaintiff further argued that any delay should be attributed to the USPTO and not Plaintiff because the USPTO did not review the application until

ten months after the commencement date, thus preventing Plaintiff from correcting any defect until two months after the deadline to do so under Rule 1.704(c)(13). *Id.* Additionally, Plaintiff argued that because it responded to the USPTO's March 11, 2020 notice within three months of receiving the notice, this clearly indicated that Plaintiff engaged in reasonable efforts to conclude prosecution of the application. *Id.* Finally, Plaintiff argued that the USPTO's decision was contrary to the Federal Circuit's decision in *Supernus*, 913 F.3d 1351, because the delay in correcting the application was due to the USPTO's conduct during its own internal review, and there was no identifiable efforts Plaintiff could have made to conclude prosecution of the application prior to receiving the March 11, 2020 notice. AR 1273–74.

On February 24, 2023, the USPTO issued a final decision denying Plaintiff's second request for reconsideration of the PTA. AR 1285. On August 18, 2023, Plaintiff filed this civil action in accordance with 35 U.S.C. § 154(b)(4)(A). *See* Compl. ¶ 9. On January 12, 2024, Plaintiff moved for summary judgment for a corrected PTA of 91 days for the '822 patent, contending that the USPTO's calculation of a PTA of 0 days is *ultra vires* and is otherwise arbitrary, capricious, unreasonable, and unsupported by substantial evidence. Dkt. 28 at 1–2. On February 1, 2024, Defendant Kathy Vidal, in her official capacity as Director of the USPTO, filed a cross-motion for summary judgment. Dkt. 34.

Legal Standard

Summary judgment is appropriate where “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). “Where, as here, judicial review is limited to the Administrative Record and the parties agree that no genuine issues of material fact exist, the Court need only decide the relevant legal questions presented by

the suit to resolve a case on summary judgment.” *ARIAD Pharms., Inc. v. Matal*, 283 F. Supp. 3d 503, 508 (E.D. Va. 2018).

“PTA decisions ‘are reviewed in accordance with the Administrative Procedure Act’ (APA).” *Intra-Cellular Therapies, Inc. v. Iancu*, 938 F.3d 1371, 1379 (Fed. Cir. 2019) (quoting *Supernus*, 913 F.3d at 1356; then citing 35 U.S.C. § 154(b)(4)(A)). Under the APA, the USPTO’s final agency action may only be set aside if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *Intra-Cellular Therapies, Inc.*, 938 F.3d at 1379 (quoting 5 U.S.C. § 706(2)(A), (C)). “[T]he scope of review is narrow and a court may not ‘substitute its judgment for that of the agency.’” *Burandt v. Dudas*, 528 F.3d 1329, 1332 (Fed. Cir. 2008) (quoting *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). “A court reviewing the agency decision ‘must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.’” *Id.* (quoting *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974)). “An abuse of discretion occurs where the decision is based on an erroneous interpretation of the law, on factual findings that are not supported by substantial evidence, or represents an unreasonable judgment in weighing relevant factors.” *Id.* (quoting *Star Fruits v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005)).

Analysis

The issue before the Court is whether the USPTO exceeded its authority or acted in violation of the APA by calculating a PTA of zero for the ’822 patent. The parties agree that Plaintiff was entitled to 134 days of A Delay in the PTA calculation for the USPTO’s failure to issue an Office action or notice of allowance within fourteen months of the ’047 Application’s commencement date. *See* Dkt. 40 at 1 (“134 days of undisputed A [D]elay”); Dkt 41 at 4 (noting

that the parties “agree that Plaintiff was entitled to 134 days of A [D]elay”). The parties also agree that the USPTO could attribute 43 days to applicant delay pursuant to 37 C.F.R. § 1.704(c)(10) after Plaintiff filed its information disclosure statement and an amended applicant data sheet. *See* Dkt. 35 ¶ 24 (noting that the parties agreed that 43 days of applicant delay was attributed to “Post-Notice of Allowance changes to the specification.”) (citing AR 1258–60)). The dispute, therefore, lies in whether the USPTO could have, and should have, reduced the patent term to zero by attributing 141 days as additional days of applicant delay for Plaintiff’s purported failure to have the ’047 Application in condition for examination within eight months of the application’s commencement date, and not having the application in such condition until June 5, 2020. For the following reasons, the Court finds that the USPTO neither exceeded its statutory authority nor acted unreasonably, arbitrarily, or capriciously in rendering its PTA decision.

I. The USPTO Did Not Exceed Its Statutory Authority Under the PTA Statute

Plaintiff challenges the USPTO’s application of 37 C.F.R. § 1.704(c)(13) by arguing that the USPTO exceeded its statutory authority to the extent the agency adopted and interpreted the regulation to reduce the patent term in excess of the time during which Plaintiff failed to engage in reasonable efforts to conclude prosecution of the ’047 Application. *See* Dkt. 29 at 1. First, Plaintiff contends that there was no reasonable effort it could have engaged in prior to receiving the March 11, 2020 Formalities Letter because any legibility defect caused by the shading of the tables in the ’047 Application was information within the sole possession of the USPTO. *Id.* at 17–24. Next, Plaintiff argues it should not have been charged with applicant delay for the 86 days between the date of the Formalities Letter and when Plaintiff corrected the specification on June 5, 2020 because Plaintiff responded to the USPTO’s notice within three months, and Plaintiff

asserts that this response time is *per se* reasonable. *Id.* at 24–25; *see also* Dkt. 40 at 23–24. The Court will address each argument in turn.

A. Plaintiff Had Notice of the Potential Shading Issue Prior to Receiving the Formalities Letter

The PTA statute provides that “[t]he period of adjustment of the term of a patent . . . shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” 35 U.S.C. § 154(b)(2)(C)(i). In *Supernus*, the Federal Circuit found this language to be “plain, clear, and conclusive.” 917 F.3d at 1358. There, the Court held that pursuant to the statute’s plain language, “PTA reduction cannot exceed the period of time during which an applicant failed to engage in reasonable efforts. Thus, if there is no period of time during which the applicant could have but failed to engage in reasonable efforts, there can be no reduction to the PTA.” *Id.* at 1359.

Here, the USPTO, pursuant to § 154(b)(2)(C)(i) and 37 C.F.R. § 1.704(c)(13), reduced the PTA calculation to 0 days after determining that Plaintiff failed to take reasonable efforts to conclude prosecution of the application by not having the patent specification in condition for examination within eight months of the application’s commencement date. *See* AR 1288. The USPTO explained that it denied Plaintiff’s request for redetermination of the PTA because the ’047 Application “was not in condition for examination as defined under 37 CFR 1.704(f) until June [5], 2020” as the shading in the tables on pages 80–84 and 139 of the ’047 Application prevented the application from being in compliance with Rule 1.52. *See* AR 1288–89.

Plaintiff argues that the USPTO’s application of Rule 1.704(c)(13) violates § 154(b)(2)(C)(i) and is contrary to the Federal Circuit’s holding in *Supernus* because it imposes reductions of the PTA without proper regard to whether any delay is due to applicant delay, and it reduces the term adjustment in excess of the time during which an applicant fails to engage in

reasonable efforts. Dkt. 29 at 21. More specifically, as it relates to the '047 Application, Plaintiff argues that there was no identifiable effort it could have taken to make the application in condition for examination without first receiving notice from the USPTO as to the possible shading defect. *Id.* at 21–23. For its part, the USPTO, in its denial decision, acknowledged that Plaintiff “did not receive notification of the defects of the application at an earlier time” but stated that it was nevertheless Plaintiff’s “responsibility to present the application papers in a form having sufficient clarity and contrast between the background of the paper and the writing thereon to permit the Office to electronically reproduce the papers[.]” AR 1290.

In *Supernus*, the Federal Circuit found that the USPTO’s assessment of applicant delay in the case had exceeded the statutory limitations for PTA reduction because there was no feasible effort the patent applicant could have taken. 913 F.3d at 1360. More specifically, the Court found that because pertinent documentation had not yet existed following the applicant’s request for continued examination, there was no reasonable effort the applicant could have engaged in to conclude prosecution of the patent. *Id.* Defendant argues that unlike in *Supernus*, there was an identifiable effort Plaintiff could have taken to conclude processing or examination of the application. That action would have been to not use shading in the tables since guidance from the USPTO put Plaintiff on notice that the use of shading may impact legibility of text. Specifically, § 608.01(I) of the Manual of Patent Examining Procedure (“MPEP”), which addresses paper requirements of a patent application, states

Legibility includes ability to be photocopied and scanned so that suitable reprints can be made and paper can be electronically reproduced by use of digital imaging and optical character recognition. This requires a high contrast, with black lines and a white background. Gray lines and/or a gray background sharply reduce photo reproduction quality.

MPEP § 608.01(I) (9th ed Aug. 2017). It further states that “[a]pplicants must make every effort to file patent applications . . . in a form that is clear and reproducible. If the papers are not of the required quality, substitute papers of suitable quality will be required.” *Id.* (citing 37 C.F.R. § 1.125 and MPEP § 608.01(q)). According to Defendant, in light of this guidance—which existed during the relevant time period of this instant action—Plaintiff had notice that the use of gray shading could affect legibility. Defendant asserts that Plaintiff could have therefore filed the application without the gray shading or submitted a corrected specification within the eight months following the application’s commencement date. *See* Dkt. 35 at 19–22. The Court agrees.

Plaintiff raises three arguments in opposition to Defendant’s reliance on MPEP § 608.01(I) in explaining the USPTO’s decision to charge Plaintiff with the 141 days of applicant delay under Rule 1.704(c)(13): (1) the MPEP is not binding and does not have the force of law; (2) MPEP § 608.01(I) is not cited in the Administrative Record; and (3) both the then-existing and correct version of MPEP § 608.01(I) do not forbid the use of gray shading. *See* Dkt. 40 at 2, 8–9, 17–19, n. 9, 24–27. The Court is unpersuaded by Plaintiff’s arguments.

First, it is undisputed that the MPEP is not binding law. Nevertheless, “the MPEP [is] commonly relied upon as a guide to patent attorneys and patent examiners on procedural matters[.]” *Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1439 (Fed. Cir. 1984), *abrogated on other grounds by Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763 (1992). Indeed, the fact that Plaintiff cited the MPEP in its opening brief in support of its motion for summary judgment is evidence that the manual is a commonly utilized guide for patent attorneys and applicants, and that Plaintiff itself was aware of the manual. *See* Dkt. 29 ¶ 2 (citing MPEP § 1842(VII)(A) in explaining how the filing date of an international application is determined). Moreover, the Federal Circuit has consistently held, “[a]lthough the MPEP does not have the force of law, it is

entitled to judicial notice so far as it is an official interpretation of statutes or regulations with which it is not in conflict.” *Hyatt v. United States Patent and Trademark Office*, 48 F.4th 1347, 1351–52 (Fed. Cir. 2022) (quoting *Airbus S.A.S. v. Firepass Corp.*, 793 F.3d 1376, 1380 (Fed. Cir. 2015) (cleaned up)). Here, MPEP § 608.01(I) expressly incorporates 37 C.F.R. § 1.52 to explain in greater detail the agency’s requirements regarding application papers. *See* MPEP § 608.01(I). Thus, while Rule 1.52(a)(1)(v) simply states that papers must be in a form having sufficient clarity and contrast, MPEP § 608.01(I) provides guidance as to what this entails, including guidance to patent applicants that the use of a gray background sharply reduces reproducibility and may affect legibility.

As noted above, MPEP § 608.01(I) also incorporates language from Rule 1.125 which states, in relevant part, that if “the legibility of the application papers renders it difficult to consider the application, or to arrange the papers for printing or copying, the Office may require the entire specification . . . be rewritten[.]” 37 C.F.R. 1.125(a). Pursuant to this regulation, the USPTO issued the March 11, 2020 Formalities Letter notifying Plaintiff that the shading in the tables prevented the application from being in compliance with Rule 1.52 and that Plaintiff would need to “furnish a substitute specification in compliance with 37 CFR 1.52 and 1.125(a)” including a “substitute specification [that was] in form without markings. *See* MPEP 608.01(q).” AR 469. The language of the March 11, 2020 Formalities Letter mirrors what is stated in MPEP § 608.01(I). *See* MPEP § 608.01(I) (“If the papers are not of the required quality, substitute papers of suitable quality will be required. *See* 37 CFR 1.125 for filing rewritten papers constituting a substitute specification required by the Office. *See also* MPEP § 608.01(q).”).

Therefore, although MPEP § 608.01(I) is not cited in the Administrative Record, the Court is able to reasonably discern from both the Formalities Letter and the USPTO’s denial decision

that concern about the use of gray shading, as articulated in MPEP § 608.01(I), formed the basis of the USPTO's determination that the '047 Application was not in condition for examination.⁴ As relevant case law makes clear, a court must "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Bowman Transp., Inc.*, 419 U.S. at 285–86; *see also Mountain Valley Pipeline, LLC v. N.C. Dep't of Env't Quality*, 990 F.3d 818, 832 (4th Cir. 2021) (finding that although the state agency's decision did not directly cite to North Carolina's general statute or administrative code, the Court could reasonably discern from the language of the agency's decision that said laws and rules were the basis of the agency's decision). Furthermore, while Plaintiff is correct that MPEP § 608.01(I) does not explicitly forbid the use of gray shading, the guideline clearly states that the requirement that application papers be legible such that the text may be electronically reproduced "requires a high contrast, with black lines and a white background." MPEP § 608.01(I). It is undisputed that the initial specification of the '047 Application included tables with gray shading instead of a white background.

In short, the Court agrees with Defendant that prior to receiving the March 11, 2020 Formalities Letter, Plaintiff was put on notice, via 37 C.F.R. § 1.52 and MPEP § 608.01(I), that the use of gray shading in the patent specification could impact legibility of the application's text and prevent the application from being in condition for examination. Therefore, Plaintiff could have submitted either an initial specification without gray shading or a substitute specification without said shading within the eight-month period following the application's commencement

⁴ For this reason, the Court does not find that Defendant's reference to MPEP § 608.01(I) to support its motion for summary judgment is *post hoc* rationalization but is rather further clarification of the already proffered reasons for which the USPTO denied Plaintiff's request for reconsideration of the PTA calculation.

date, and Plaintiff need not have waited for the USPTO to notify it of the potential problem.⁵ Thus, unlike in *Supernus*, there was an identifiable and reasonable effort Plaintiff could have engaged in to conclude processing or examination of the '047 Application: Plaintiff could have submitted a specification without gray shading prior to the expiration of Rule 1.704(c)(13)'s eight-month grace period. Plaintiff failed to do so. In accordance with 35 U.S.C. § 154(b)(2)(C)(i) and 37 C.F.R. § 1.704(c)(13), the USPTO determined that Plaintiff's conduct constitutes a failure to engage in reasonable efforts that is attributed as applicant delay. The Court does not find this to be in contravention of the PTA statute.

The Court acknowledges Plaintiff's argument that whether an applicant is subject to a PTA reduction under Rule 1.704(c)(13) is driven by when the USPTO notifies an applicant of the shading issue. More specifically, Plaintiff argues that under the USPTO's application and interpretation of Rule 1704(c)(13),

if the PTO notifies the applicant of a shading issue four months after the application is filed, and the applicant fixes the shading issue four months later, there will be no applicant delay. But if the PTO takes two years to notify the applicant of the shading issue, and the applicant immediately fixes it, the applicant will be charged with 16 months of applicant delay (all the time after eight months during which the application was purportedly not in a condition for examination).

Dkt. 29 at 21. Defendant does not dispute the accuracy of Plaintiff's assertion regarding these hypothetical situations but contends that "[t]hese hypothetical results do not run contrary to the language of 35 U.S.C. § 154(b)(2)(C)(i) or 37 C.F.R. § 1.704(c)(13)."⁶ Dkt. 35 at 24. Rather,

⁵ Indeed, as Defendant notes, and Plaintiff does not dispel, other patent applicants have corrected their specifications and removed any shading on their own without having first received the agency's notice of the issue. *See* Dkt. 35 at 21; *see also* Dkt. 35-1 at 933–36.

⁶ Defendant does, however, argue that Plaintiff waived this argument by not raising it during the administrative proceedings. *See* Dkt. 35 at 22–25. However, because the Court finds that this argument is reasonably related to Plaintiff's broader argument that Plaintiff could not have been

Defendant asserts that any “discrepancy as to when the USPTO alerts the applicant of a shading problem is irrelevant” because “the agency’s guidance on legibility . . . is always publicly available to any applicant” regardless of when the USPTO issues a Formalities Letter. *Id.* at 25.

Despite the plausibility of the differing results hypothesized by Plaintiff, the Court does not find that the USPTO’s application and interpretation of Rule 1.704(c)(13) runs afoul of the PTA statute. First and foremost, the Court agrees with Defendant that Congress did not impose on the USPTO a statutory obligation to issue a Formalities Letter within a specific period of time. Relevant to this case is subsection 154(b)(1)(A) of the PTA statute, which provides that the USPTO’s failure to issue “at least one of the notification under section 132 [Office actions] or a notice of allowance under section 151” within fourteen months of an international application’s commencement date shall extend the term of the patent by one day for each day until the USPTO issues the said notification or notice of allowance. 35 U.S.C. § 154(b)(1)(A). Plaintiff does not dispute the fact that a Formalities Letter neither constitutes a notification under section 132 or a notice of allowance under section 151. Thus, though subsection 154(b)(1)(A) starts the clock for when the USPTO must take action with respect to a patent application on the date the application commences, the statute does not impose a specific time in which the agency must provide a Formalities Letter; and Plaintiff points to nothing to the contrary.⁷ Therefore, when the USPTO issues a Formalities Letter is left to the agency’s discretion.

made aware of the shading defect until it received the Formalities Letter, the Court will consider and address the merits of this argument.

⁷ Plaintiff does, however, argue that the USPTO, in promulgating Rule 1.704(c)(13), “said the pre-examination process should be completed within five months” and therefore, the agency failed to act in accordance with its own regulations in not issuing the March 11, 2020 Formalities Letter sooner. *See* Dkt. 40 at 15, 31 (citing Patent Law Treaty Changes, 78 Fed. Reg. 62368–01, 62384 (Oct. 21, 2013)). However, the part of the Federal Registry that Plaintiff cites concerned “patent laws in effect between 2000 and 2012.” Patent Law Treaty Changes, 78 Fed. Reg. at 62384.

Moreover, as noted earlier, subsection 154(b)(2)(C)(i) states that “[t]he period of adjustment of the term of a patent . . . shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.” 35 U.S.C. § 154(b)(2)(C)(i). The Federal Circuit has stated that in issuing this statutory provision, “Congress’s primary intent was to penalize applicant *conduct* as opposed to the results of such conduct.” *Gilead*, 778 F.3d at 1348. A patent applicant’s use of shading in the patent specification is, by definition, an action or conduct that the applicant chooses to engage in, irrespective of the USPTO’s formalities review and its issuance of a Formalities Letter. Thus, the Court disagrees with Plaintiff that the USPTO’s application of Rule 1.704(c)(13) imposes a PTA reduction without regard to applicant conduct. *See* Dkt. 29 at 21. It is an applicant’s conduct, and in this case, Plaintiff’s, that turns on whether the applicant is subject to a PTA reduction under Rule 1.704(c)(13). Had Plaintiff received earlier notice from the USPTO of the shading issue, Plaintiff may have been able to fix the problem before the expiration of Rule 1.704(c)(13)’s eight-month grace period. However, Plaintiff chose to submit a specification that included gray shading despite being on notice, vis-à-vis publicly available agency guidance, that such shading could affect legibility and prevent the application from being in condition for examination. In accordance with its statutory authority, the USPTO determined that Plaintiff’s failure to provide the specification in condition for examination constitutes a failure to engage in reasonable efforts that warranted a reduction of the PTA calculation. The Court finds this to be consistent with the statute.

Indeed, at the time said laws were in effect, the USPTO required applications to be in condition for examination within five months. However, Rule 1.704 later amended this to provide that an application needs to be in condition for examination within eight months. *See id.* at 62384–85. Thus, Plaintiff’s argument is inapposite.

B. The USPTO Had the Authority to Attribute Plaintiff's Response Time as Applicant Delay

Plaintiff further argues that the USPTO exceeded its authority to reduce the patent term by attributing its 86-day response time to the Formalities Letter as applicant delay, because Plaintiff's response time demonstrates a reasonable effort to conclude prosecution of the application. Dkt. 29 at 24–25; *see also* AR 1273. More specifically, Plaintiff argues that Congress has limited the USPTO's authority to attribute response time as applicant delay by providing in subsection 154(b)(2)(C)(ii) of the PTA statute that, “an applicant [is] deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request[.]” Dkt. 29 at 24 (quoting 35 U.S.C. § 154(b)(2)(C)(ii)).⁸

The plain language of subsection 154(b)(2)(C)(ii), however, provides that the statutory provision applies to “adjustments to patent term made under the authority of paragraph (1)(B) [B Delay][.]” 35 U.S.C. § 154(b)(2)(C)(ii). It is undisputed that B Delay calculations are not at issue in this case. *See* AR 1258–59, 1286–87. Nevertheless, Plaintiff argues that “through the structure of 35 U.S.C. § 154(b)(2)(C)[.]” Congress indicated that responding to the USPTO within three months is *per se* reasonable. Dkt. 40 at 24. However, this Court “must give effect to the unambiguously expressed intent of Congress.” *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013). Here, Congress expressly provided that within the context of B Delays, a three-month

⁸ Defendant argues that Plaintiff waived any argument for a lower applicant delay number relying upon the language of § 154(b)(2)(C)(ii). Dkt. 35 at 27. However, as noted above, Plaintiff did raise the argument that a three-month response time is reasonable during the administrative proceedings. *See* AR 1273. Therefore, the Court will consider and address the merits of this argument.

response time to a USPTO notice is an example of a reasonable effort. Congress did not, however, apply such a rule to cases, such as this present one, involving A Delays.

Instead, as noted earlier, Congress gave the USPTO the authority to “prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” 35 U.S.C. § 154(b)(2)(C)(iii). The Federal Circuit has stated that the broad language of subsection 154(b)(2)(C)(iii) “demonstrates Congress intended the PTO to employ its expertise in identifying applicant conduct demonstrating a lack of ‘reasonable efforts to conclude processing or examination of an application.’” *Gilead*, 778 F.3d at 1349 (citation omitted). Here, in accordance with its delegated authority, the USPTO promulgated Rule 1.704(c)(13), which states, in relevant part, that “the period of adjustment . . . shall be reduced by the number of days, if any, beginning on the day after the date that is eight months from . . . the date of commencement of the national stage under 35 U.S.C. 371(b) or (f) in an international application and ending on the date the application is in condition for examination[.]” 37 C.F.R. § 1.704(c)(13). Thus, through its promulgation of Rule 1.704(c)(13), the USPTO has determined that for every day an international patent application is not deemed to be in condition for examination following the eight-month period, each day constitutes a failure to engage in reasonable efforts to conclude processing or examination of an application. *See id.*; *see also* Dkt. 41 at 23 (“What Plaintiff fails to appreciate is that during the time Plaintiff spent remedying the deficiencies identified in the Formalities Letter, that *still properly counted* as time that Plaintiff failed to take reasonable efforts to advance or conclude prosecution under 35 U.S.C. § 154(b)(2)(C)(i) because gray shading remained in the ’047 Application.”).

The Court does not find that such a determination is contrary to the PTA statute. Indeed, such a determination is supported by the Federal Circuit’s finding that a delay in a patent examiner’s ability to review a certain application may “make it increasingly difficult for the [US]PTO to satisfy the statutorily-mandated time requirement stipulated in § 154(b)(1)(A)(ii)” for not only the application at issue, but for other applications as well. *See Gilead*, 778 F.3d at 1351. For this reason, and for the reasons stated above, the Court finds that the USPTO’s interpretation and application of Rule 1.704(c)(13) in this instant action is consistent with the PTA statute, and the agency did not exceed its statutory authority in attributing Plaintiff’s response time as applicant delay that reduced the patent term adjustment for the ’822 patent.

II. The USPTO Did Not Act Contrary to the APA As Its Decision is Not Unreasonable, Arbitrary, Capricious, or An Abuse of Discretion

Plaintiff further argues that even if the Court found the USPTO’s decision to be consistent with the PTA statute, the decision is nevertheless an abuse of discretion or arbitrary and capricious, and therefore violates the APA. Dkt. 29 at 1. Specifically, Plaintiff argues that (1) the USPTO’s decision cannot be reconciled with two other patent applications—the ’625 and ’594 Applications—which demonstrate the arbitrariness of the agency’s application of Rule 1.704(c)(13); and (2) the USPTO failed to present substantial evidence that the use of gray shading in the ’047 Application turned the text illegible after electronic reproduction. *See id.* at 27–28, 30; *see also* Dkt. 40 at 28–35.⁹

⁹ In its opening brief, Plaintiff also argued that the USPTO acted arbitrarily and capriciously by attributing applicant delay to Plaintiff under Rule 1.704(c)(13) but not for Plaintiff’s failure to timely pay certain national stage fees. Dkt. 29 at 28–29. In response, Defendant argued that the fees Plaintiff referred to were unrelated to the requirements of Rules 1.704(c)(13) and 1.704(f) and therefore, the USPTO could not assess applicant delay for the Plaintiff’s untimely payment of these fees. Dkt. 35 at 25–26; *see also* 37 C.F.R. § 1.704(f). Because Plaintiff does not respond to Defendant’s argument, and the Court finds that Defendant’s claim is soundly based in the relevant regulatory provisions, the Court need not address this issue further.

Defendant argues that Plaintiff has waived these arguments by not raising them first during the administrative proceedings. *See* Dkt. 35 at 22–27. The Court agrees. The Court finds nowhere in the Administrative Record where Plaintiff raised these arguments before the agency, and Plaintiff cites to nothing indicating otherwise.¹⁰ Therefore, as a procedural matter, Plaintiff has forfeited the right to have the Court consider them. *See Californiaa*, 2021 WL 6196996, at *5 n.3 (“Issues not raised before an agency are waived and will not be considered by a court on review.” (quoting *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297 (D.C. Cir. 2004))). Even considering the actual substance of Plaintiff’s arguments, the Court is unpersuaded and does not find that the USPTO’s decision violates the APA.

Plaintiff’s first point of contention is that the USPTO has inconsistently applied Rule 1.704(c)(13), as demonstrated by the PTA decisions in two other cases, the ’625 and ’594 patent Applications. With respect to the ’625 Application, the USPTO did not assign any applicant delay for the applicant’s failure to present the application in condition for examination within the eight-month deadline even though, like in this instant action, the applicant did not file a corrected specification until after receiving the agency’s Formalities Letter. Dkt. 29 at 28; Dkt. 35 at 22. Defendant acknowledges that the facts of the ’625 Application are nearly identical to those of this present case but argues this was a mistaken decision that should not call into question the USPTO’s otherwise consistent application of Rule 1.704(c)(13). Dkt. 35 at 23. In support of this argument, Defendant has identified at least five other instances in which, like this present action, the USPTO

¹⁰ The Court does note that Plaintiff did argue before the USPTO that, in accordance with Rule 1.52(a)(1)(v), the text in the shaded tables of the ’047 Application was sufficiently clear and had sufficient clarity between the text and the paper’s background. AR 1272–73. However, Plaintiff did not raise the substantial evidence argument or the other APA argument identified above.

attributed as applicant delay the period of time it took an applicant to file corrected specifications outside of the eight-month deadline. *Id.* at 18.

As it pertains to the '594 Application, Defendant acknowledges that the USPTO failed to catch the gray shading problem sooner and issued a notice of allowance before a formalities letter. Dkt. 41 at 20. However, Defendant argues that the case nevertheless provides further illustration of the agency's practice of assessing applicant delay for the untimely removal of gray shading because, under relevant regulation in effect at the time, the USPTO assessed 26 days of applicant delay following the applicant's filing of an amended specification. *Id.*

Courts have held that a prior erroneous action does not render an agency's decision arbitrary, capricious, or an abuse of discretion in the face of a demonstrated consistent agency practice. *See Univ. of Massachusetts v. Kappos*, 903 F. Supp. 2d 77, 89 (D.D.C. 2012) (finding that the USPTO did not act arbitrarily and capriciously in the case at hand because the agency "appear[ed] to have returned to its usual practice" following a prior decision); *Boehringer Ingelheim Pharma GMBH & Co. KG v. FDA*, 195 F. Supp. 3d 366, 382 (D.D.C. 2016) (finding that single inconsistent determination that stood in contrast to a thirty year practice did not make the agency's decision arbitrary or capricious, particularly when the agency had shown that its "determination in [the instant] case [was] consistent with numerous similar determinations made in other cases"). Here, Defendant has acknowledged that the USPTO erred in making the PTA determination for the '625 application and for not catching the shading issue in the '594 Application prior to issuing the notice of allowance; but Defendant has shown that the agency's decision in this case is consistent with the agency's decision in several other similar cases. Considering this, and given the APA's deferential standard, the Court does not find that the USPTO's decision to calculate a PTA of 0 for the '822 patent is arbitrary and capricious.

For similar reasons, Plaintiff's argument that the USPTO's decision is an abuse of discretion because the agency failed to present substantial evidence of any legibility issue also fails. Specifically, Plaintiff contends that the text in the gray tables of the '047 Application was sufficiently clear and readily legible, and as such, because the USPTO failed to present evidence showing that electronic reproduction of the application turned the text illegible, the agency's decision to apply Rule 1.704(c)(13) is violative of the APA. *See* Dkt. 29 at 29–30. The Court, however, finds that Plaintiff's argument is foreclosed by the Federal Circuit's decision in *Gilead*. There, the Federal Circuit found that under a reasonable interpretation of § 154(b)(2)(C)(iii), "Congress intended to sanction not only applicant conduct or behavior that result in actual delay, but also those having the potential to result in delay irrespective of whether such delay actually occurred." *Gilead*, 778 F.3d at 1349.

Applying this reasoning to the case at hand, the Court finds that the USPTO need not have shown that the gray shading in the '047 Application turned the text illegible upon electronic reproduction, so long as the agency believed that it could, and consequently, would prevent the application from being in condition for examination. The USPTO consistently explained to Plaintiff that the agency believed the '047 Application was not in compliance with Rule 1.52(a)(1)(v), which is incorporated by reference into Rule 1.704(f), because of the gray shading in the tables on pages 80–84 and 139 of the Application. As discussed in depth above, guidance from the USPTO explains thoroughly the agency's concern with the issue of gray shading, and specifically, how it may impact legibility. Therefore, it was reasonable, and not a clear error of judgment, for the USPTO to determine that the gray shading could impact the legibility of the text

and find that the application was not in condition for examination. Accordingly, the Court does not find that the agency's decision violates the APA.¹¹

Conclusion

In sum, and for the foregoing reasons, this Court finds that the USPTO's PTA calculation of zero (0) days for the '822 patent is neither contrary to the statute nor an abuse of discretion or arbitrary and capricious. Accordingly, it is hereby

ORDERED that Plaintiff's Motion for Summary Judgment (Dkt. 29) is **DENIED**; it is further

ORDERED that Defendant's Cross-Motion for Summary Judgment (Dkt. 34) is **GRANTED**; and it is further

ORDERED that the Clerk is **DIRECTED** to enter judgment in favor of Defendant in accordance with Rule 58 of the Federal Rules of Civil Procedure.

It is **SO ORDERED**.

Dated: July 19, 2024



Patricia Tolliver Giles
United States District Judge

¹¹ Because the parties agree that Plaintiff's Takings Clause claim rises and falls with the APA claim, then this claim also fails. *See* Dkt. 35 at 28 n.11 (“[Plaintiff’s Fifth Amendment takings] claim rises and falls with the APA claim.”); Dkt. 40 at 35 (contending that, to the extent Plaintiff’s APA claim succeeds, “so should its takings claim.”); *see also Idorsia Pharm. Ltd. v. Iancu*, 393 F. Supp. 3d 445, 456 (E.D. Va. 2019) (“[P]laintiff’s Fifth Amendment claim fails for the same reasons as plaintiff’s challenges to the PTO’s PTA determination brought under § 154(b)(4)(A) and the APA.”), *aff’d*, 811 F. App’x 650 (Fed. Cir. 2020).